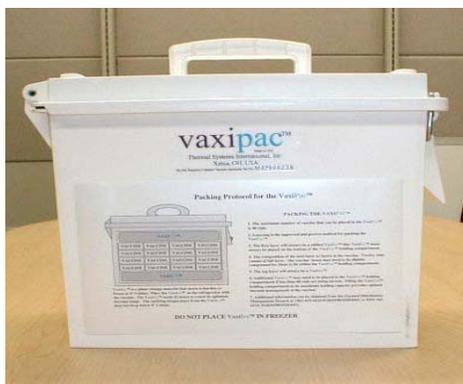
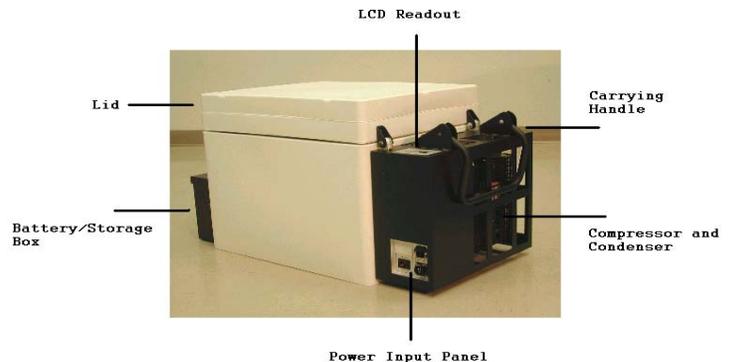




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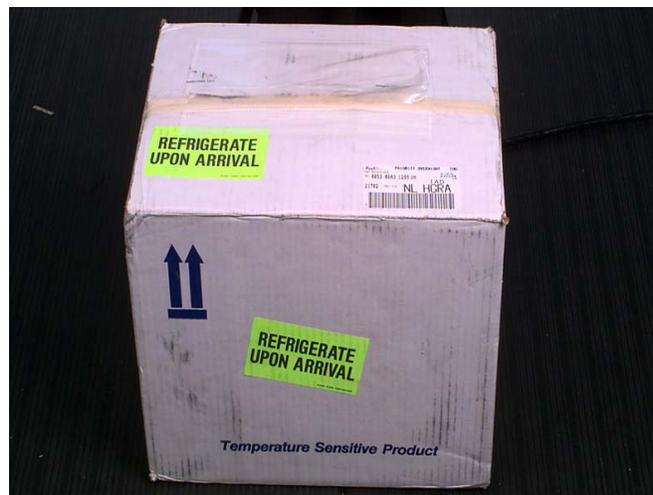
Equipment Used to Support Cold Chain Distribution





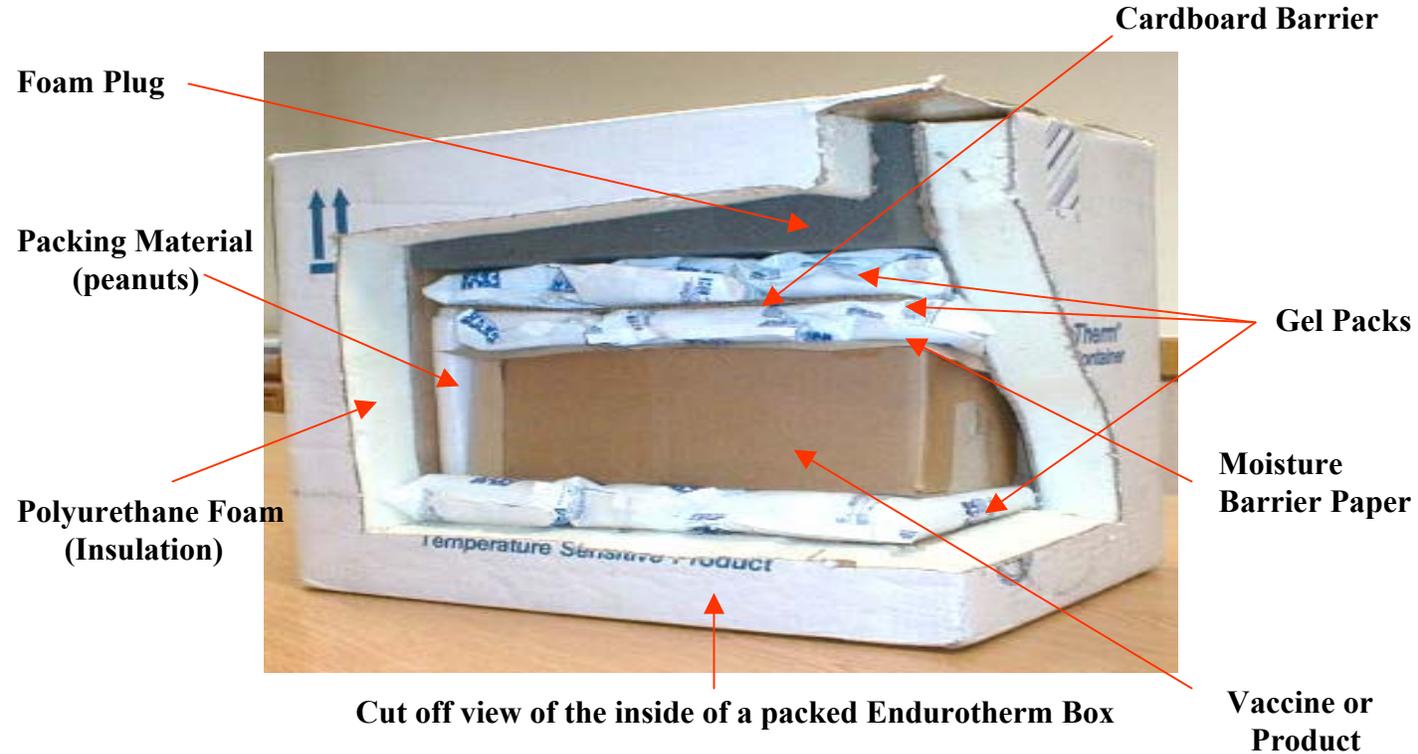
U.S. Army Medical Materiel Agency (USAMMA)/Distribution Operations Center (DOC)

Endurotherm Insulating Shipping Containers and Packing Protocols for Temperature Sensitive Products



Manufacturer: Insulating Shipping Containers (ISC), Inc., Phoenix, AZ

Cold Chain Management employs a common sense approach that keeps products in the correct temperature ranges from the initial entry into DoD channels until administration/issue to the patient or end user. The Distribution Operations Center at USAMMA developed and validated many of the principles and methods from lessons learned during the initiation of the Anthrax Vaccination Immunization Program (AVIP).



Endurotherm Box:

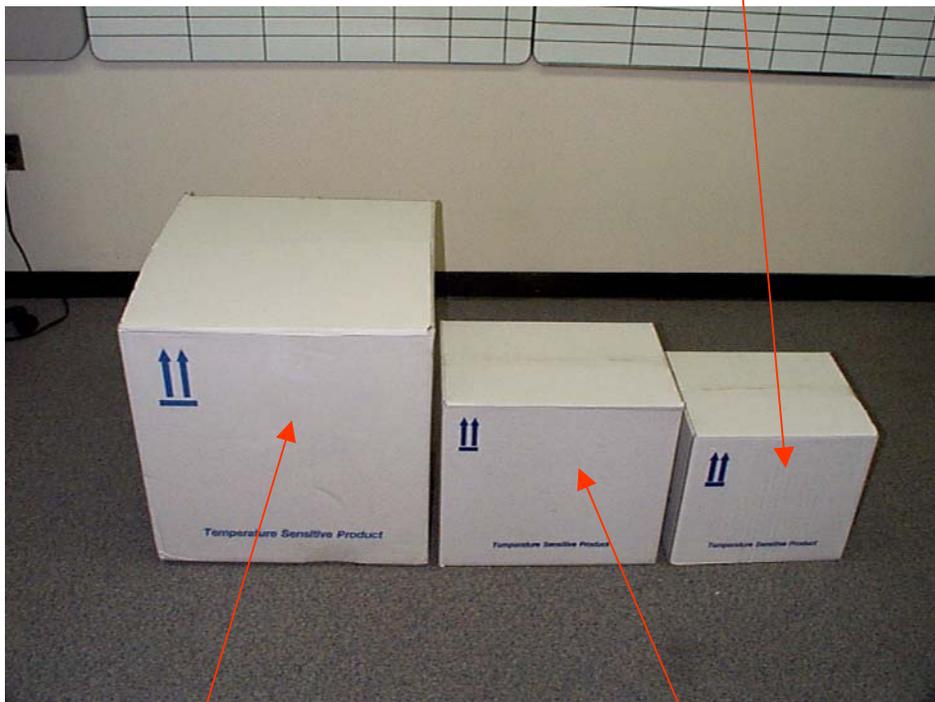
Material: It is comprised of two corrugate layers injected with 2 inches of polyurethane foam within a mold. The end product is a rigid, one piece, three layer laminated container.

The following are weight and amount of gel packs for each complete box:

- **Small Box:** packed weight - 20 lbs, with (10) 24 oz Gel packs.
- **Medium Box:** packed weight - 30 lbs, with (14) 24 oz Gel packs.
- **Large Box:** packed weight - 120 lbs, with (21) 48 oz Gel packs.

A complete packing system was designed using the Endurotherm boxes to ensure the cold chain distribution process is not broken. There are three different sizes small, medium and large. The boxes have gone through various testing protocols and they can maintain the required temperature for up to 7 days.

E-36-2 (Small container) has a inside dimension of 10-5/8 in (length) by 7-7/8 in (width) by 7 in (depth).



E-327 (Large container) has an inside dimension of 18-1/2 in (length) by 18-1/4 in (width) by 16-3/4 in (depth) .

E-65 (Medium container) has a inside dimension of 13-7/8 in (length) by 7-7/8 in (width) by 10 in (depth).

Refrigerants

Gel packs are coolant or refrigerants used to maintain desired temperature levels (refrigerated or frozen) inside the Endurotherm boxes during shipping. When packing refrigerated products gel packs must be refrigerated at +4° Celsius and for frozen products the temperature should be at -17° Celsius for at least 24 hours prior use.



**Medium Gel Packs
(24 oz ea) are used in Medium
and Small Endurotherm Boxes**

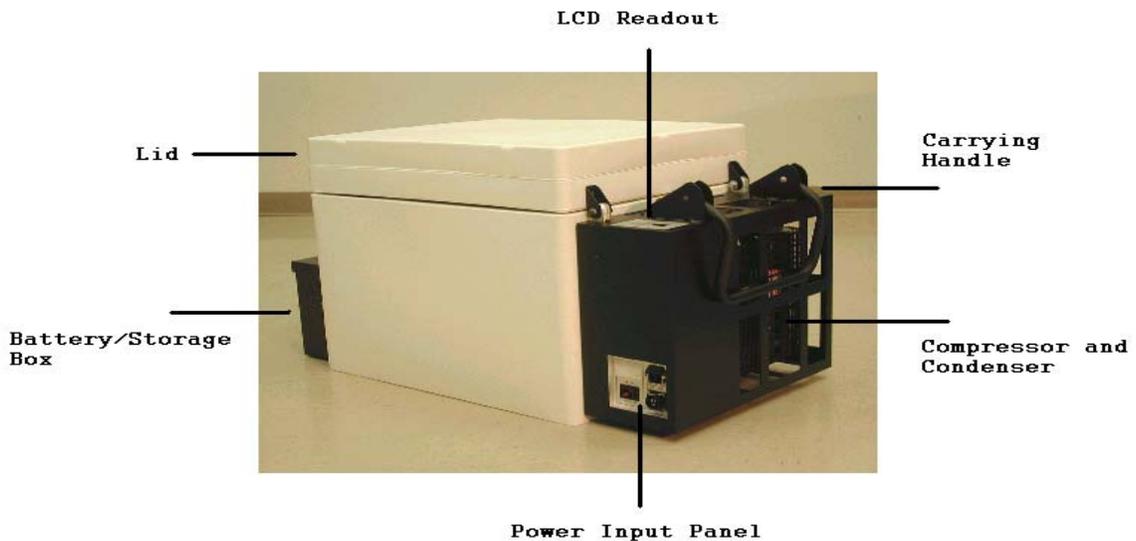
Gel Packs

**Large Gel Packs
(48 oz ea) are used in
Large Endurotherm Boxes
only.**



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VaxiCool Refrigerator/Freezer



Manufacturer: Energy Storage Technologies (EST), Dayton, OH

The VaxiCool is a commercially procured, high-efficiency refrigerator or freezer system designed for the local transport, temporary storage and re-distribution of temperature-sensitive pharmaceuticals. It comes in two models, VXC-1 and VXC-2. The VXC-1 model is a refrigerator only, the VXC-2 is both refrigerator and freezer. No NSN has been assigned to the VXC-2 yet.

----Model: VX30PPNR (VXC-1)

----NSN: 4110-01-459-3690

----Material: It is comprised of Vacupanel Insulation designed to maintain vaccine at 2° - 8° Celsius.

----Payload area: Approximately 1 cubic foot.

----Alternate Power sources: 110 AC (220 w/special cable), car battery, solar panels, car cigarette lighter.

----Batteries: 2-12Volt/14 Amp or 2-12Volt/14 Amp gel cell batteries.

When 2-12 Volt/14 Amp batteries are installed and fully charged, the VaxiCool can maintain temperatures on internal batteries for up to 5 days, when using 2-12 Volt/20 Amps it can maintain temperature for up to 6 to 7 days after being disconnected from an AC power source. Due to its insulation capabilities it can possibly add 16-24 hours more if the lid is kept closed.

*** Intra-Theater Distribution utilizes Express Carriers to transport the Vaxicools which are strategically pre-position throughout the world to help with intra-theater distribution.**



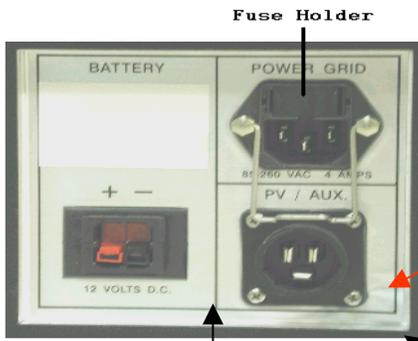
Power panel contains solar input plug, AC power from 90-270 Volts and accessory plug for car battery and car cigarette lighter.



The VaxiCool has an inside dimension of 14" (length) by 10-1/2" (width) by 10" (depth), its payload can be from 1 to 400 Vials.

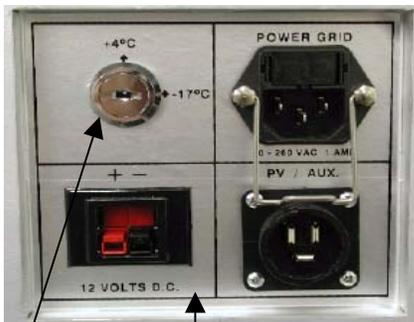
Battery box contains 2 -12 Volt/14 or 2-12 Volt/20 Amp dry gel-cell batteries.

The system is comprised of a super efficient compressor and a super insulated container using Vacupanel insulation designed to maintain vaccines at appropriate temperatures from 2°C to 8°C.



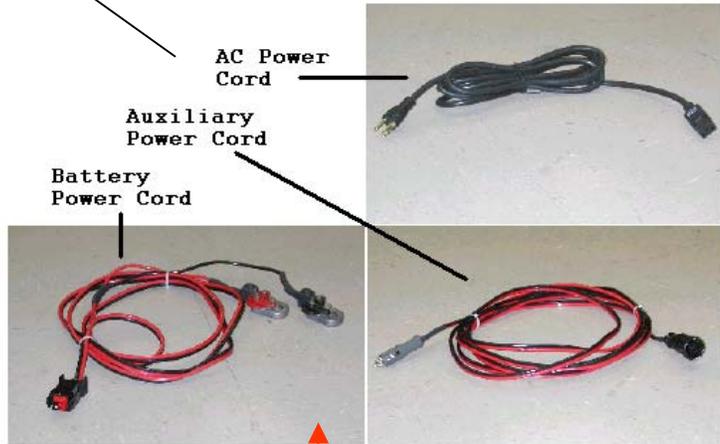
Power Input Panel (VXC-1)

The plugs for the various power sources are clearly marked. The receptacle for the power grid has a fuse holder above the plug. The wire frame that is hanging from the receptacle is used to hold an electrical cord more firmly, making it difficult to accidentally knock the cord loose.



Power Input Panel (VXC-2)

w/key switch for refrigeration/freezer mode



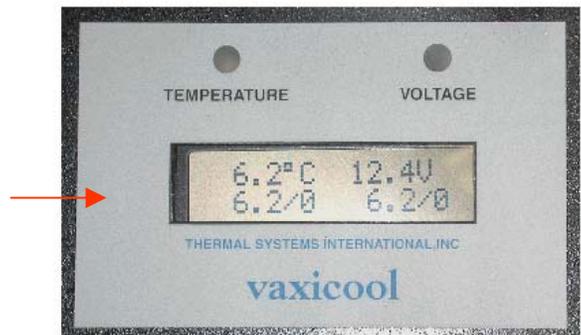
AC Power Cord

Auxiliary Power Cord

Battery Power Cord

Examples of the various power cords for the unit are shown above. There is one example of each type of plug used with the power input panel. Note that the battery cord has fittings for a typical lead acid battery, and the auxiliary power cord has a plug that fits into the common cigarette lighter receptacle.

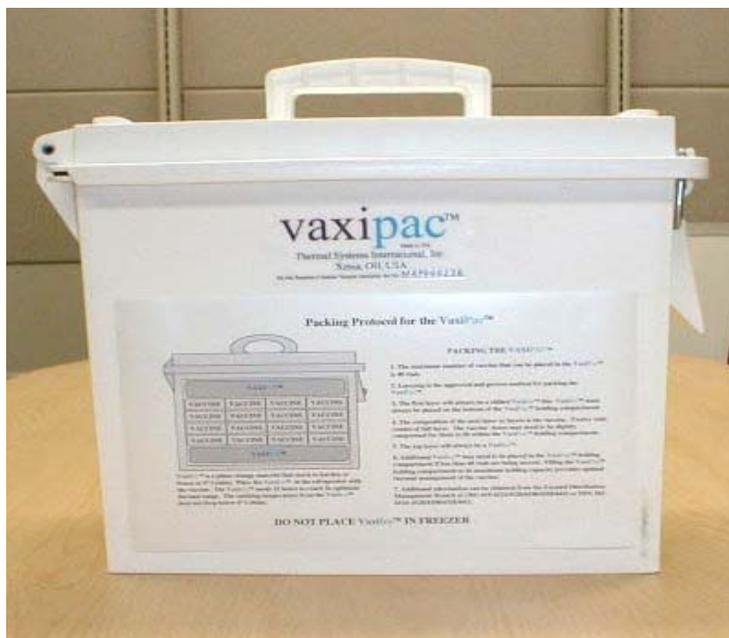
Once the unit has power, the LCD readout will begin to function. The upper left line displays the payload area current temperature and the upper right will display current voltage. The lower line will display the high and low temperatures readings that the unit experienced during the preceding seven day period. There are temperature and voltage alarms. If the temperature or voltage has exceeded safe operating ranges the unit will produce a beeping sound.





**U.S. Army Medical Materiel Agency
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VaxiPac Shipping Container



Manufacturer: Energy Storage Technologies (EST), Dayton, OH

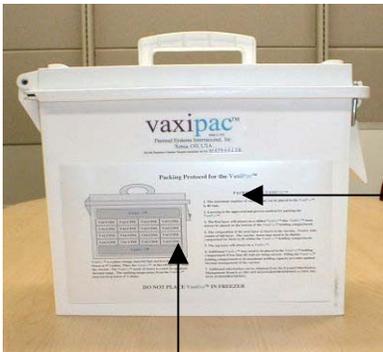
The VaxiPac is a commercially procured, high-efficiency small insulated container used for transport of vaccines and other temperature sensitive pharmaceuticals. It is used for the re-distribution of products for short movements of less than 24 hours. The container is designed to maintain the product at the appropriate temperature (2° – 8° Celsius).

----NSN: 6515-01-475-8145

----Material: It is comprised of a rugged, hard plastic material filled with Vacupanel insulation.

----Payload: 1 to 24 vials maximum.

It utilizes a specific refrigerant called VaxiSafe which is composed of a Phase Change Material (PCM) that hardens at 6° degrees Celsius and protects against varying temperatures. The VaxiSafe is an approved replacement for ice in a passive container that does not freeze products. The VaxiPac comes with 5 VaxiSafes from the manufacturer.



Walls are comprised of VacuPanel insulation

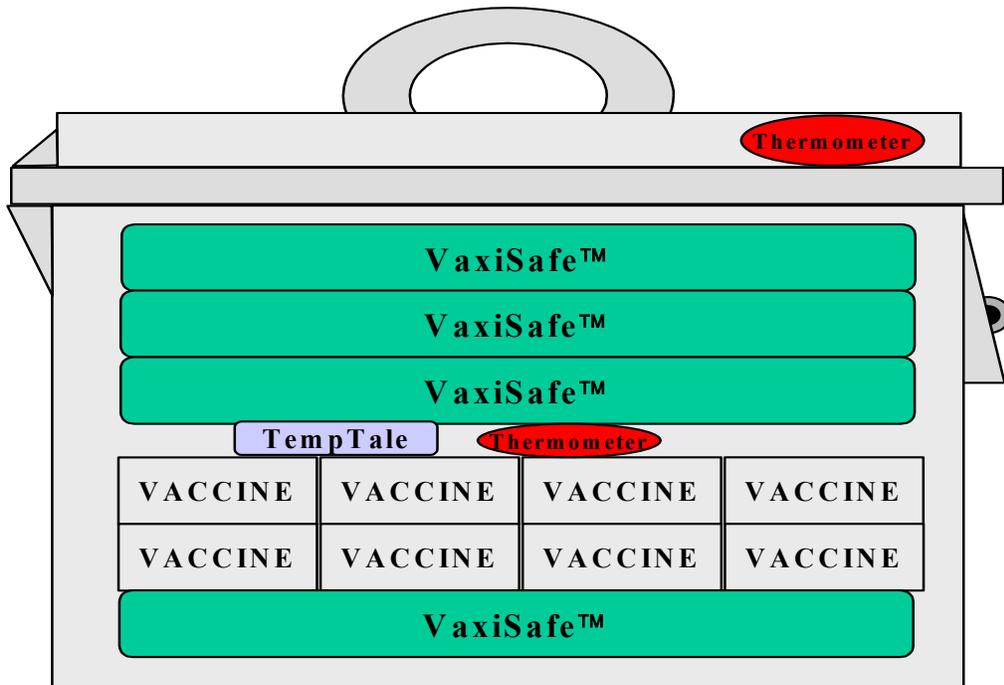
Exterior dimension of 15" (length) by 7.75" (width) by 11.38" (depth).



VaxiSafe is a Phase Change Material (PCM) that starts to harden or freeze at 6°C.

A maximum of 24 vials can be placed in the VaxiPac (a full layer consists of 12 vials).

VaxiPac Container Packing Configuration



The approved method for redistribution of temperature sensitive products is the VaxiPac.

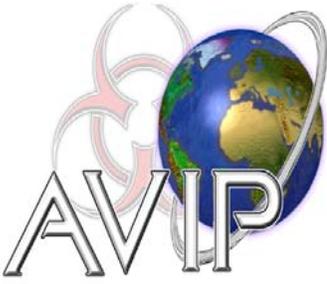
Pack the vaccine in the VaxiPac as follows:

- o Place one VaxiSafe at the bottom of the VaxiPac.
- o Place the vaccine or temperature sensitive pharmaceutical on top of the VaxiSafe.
- o Place the red thermometer next to or on top of the vaccine.
- o Place TempTale 3 Temperature monitor next to or on top of the vaccine.
- o Place the 3 or 4 remaining VaxiSafes on top of the vaccine (depending on the amount of vaccine).
- o Close the lid and secure it with a plastic seal.

How to chill the VaxiSafe:

The VaxiSafe should be chilled to 4° Celsius/39° Fahrenheit. An easy way to accomplish this is to place the VaxiSafe in the same refrigerator as the vaccine and chill for at least 24 hours. Use accurate temperature-controlled coolers or refrigerators to chill this material.

Note: Avoid deforming the physical shape or the packaging of the VaxiSafe.



**U.S. Army Medical Materiel Agency
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**TempTale 3 Multiple-Use
Temperature Monitor**



Manufacturer: Sensitech Inc, Beverly, MA

The TempTale 3 multiple use temperature monitor system provides complete time and temperature history on all of our temperature sensitive product shipments. Data collected is use to validate that our products has preserved their integrity during distribution from the manufacturer to the end user. The TempTale 3 temperature monitor is manufactured by Sensitech, Inc. This device can be set to read every ten (10) minutes for approximately two (2) weeks and record 2,000 data points. Depending on capabilities the cost for this device varies from \$34.00 -\$179.00 each.



TempTale3 (TT3)

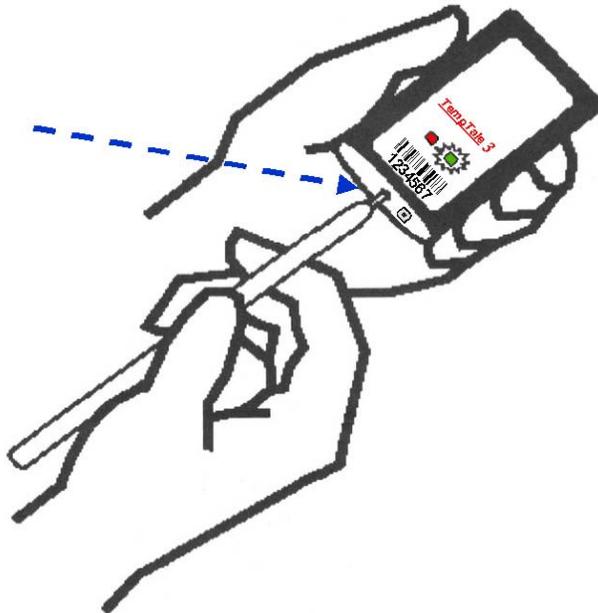
The TT3 is used by many industries to record conditions during air, marine, and land transportation, as well as to monitor environmental conditions while products are in storage. TT3's use thermistor technology to measure ambient temperatures, or they measure core temperatures with the optional probes.

TempTale3

<i>Operating Range</i>	-22°F to +185°F (-30°C to +85°C)*	
<i>Sensor Options</i>	Ambient, SS Probe, Flex Probe, Pulp Probe (16,000 data pts only)	
<i>Sensor Accuracy</i>	±2°F from -22°F to 0°F	(±1.1°C from -30°C to -18°C)
	±1°F from 0°F to +122°F	(±0.55°C from -18°C to +50°C)
	±2°F from +122°F to +185°F	(±1.1°C from +50°C to +85°C)
<i>Memory Size</i>	2,000 or 16,000 Data Points	
<i>Temperature Alarms</i>	Yes - Red/Green LED Alarm	
<i>Start-Up Delay</i>	Minimum - 0 Minutes	Maximum - 20 Days
<i>Measurement Interval</i>	Minimum - 30 Seconds	Maximum - 120 Minutes
<i>Sensor Resolution</i>	0.1° (1/10°)	

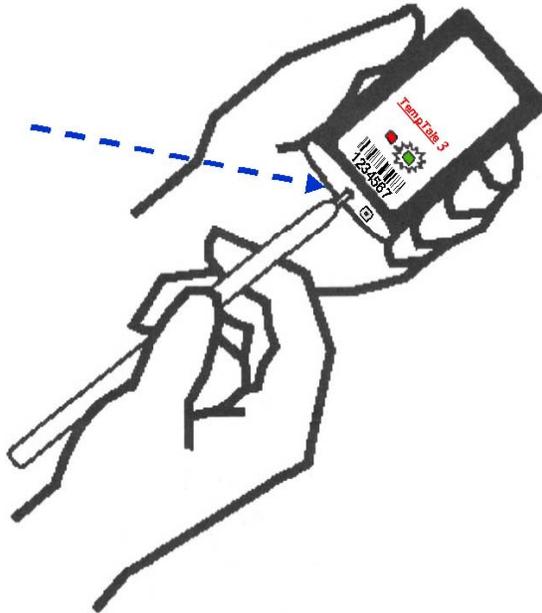
Instructions for Starting the TempTale 3 Multiple-Use Temperature Monitor

- Locate the start button on the end of the TempTale (start button is the black opening; do not insert anything into the opening with the silver ring.)
- While looking at the **red** & **green** lights on the face of the TempTale, depress the start button with a pen and release.
- When the monitor is activated the LEDs (**green light**) on the face of the monitor will flash **(8) eight** times.
- Wait about 2 minutes (start-up delay) and press the start button again, then it should blink **twice**. The monitor is now activated. Peel the paper from the adhesive strip & stick the TempTale to the product to reduce movement of the TempTale during shipment.



Instructions for Reading the TempTale 3 Multiple-Use Temperature Monitor

- Locate the start button on the end of the TempTale (start button is the black opening; do not insert anything into the opening with the silver ring.)
- While looking at the **red** & **green** lights on the face of the TempTale, depress the start button with a pen and release.
- Either the **red** light or the **green** light will flash on the monitor.
- The **green** light indicates that the shipment was completed within the set temperature limits of the monitor.
- The **red** light indicates that temperature limits set on the monitor were exceeded.



TempTale 3 Multiple-Use Temperature Monitor Graph Reading

- o This is the actual reading of a graph for a 24-hour cross- country shipment using an Endurotherm box and our validated packing protocols.
- o Graph is almost flat due to insulation of box.
- o By viewing the graph we can see the temperature of the product when it left the shipping site and when the box was opened by the customer. The sudden spike is when the box is opened.

We use a special software to download the TempTale 3 information.

TempTale Download Data

